

Exhibit 48

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

This Document Relates to All Actions

STIPULATION OF ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.

Pursuant to Special Master Report and Order No. 56, in exchange for Plaintiffs' agreement not to further examine a witness at deposition regarding the statements identified herein, Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") hereby stipulates as follows:

1. ZHP states that there are no health benefits associated with the presence of NDMA or NDEA in valsartan.
2. ZHP states that the publication *Purification of Laboratory Chemicals* (4th ed.) by W.L.F. Armarego and D.D. Perrin, which was first published in 1996 and documented scientific knowledge at that time, states on page 192 that DMF

“[d]ecomposes slightly at its normal boiling point to give small amounts of dimethylamine and carbon monoxide.”

3. ZHP states that it was required to perform a risk assessment in connection with the process change to the zinc chloride process. ZHP further states the following:
 - a. ZHP states that the scientific research relied on to use DMF as part of the zinc chloride process did not include scientific research into the potential decomposition products of DMF under the conditions of the zinc chloride process.
 - b. The risk assessment of DMF did not specifically evaluate whether DMF was degrading to yield dimethylamine as part of the zinc chloride process.
 - c. Therefore, there is no document from Shanghai SynCores or ZHP that documents that potential degradation of DMF as part of the zinc chloride process was evaluated as part of the risk assessment for the zinc chloride process.
 - d. ZHP states that it did not perform a risk assessment on the potential degradation of DMF because it did not realize that DMF would degrade in the way it ultimately degraded in the zinc chloride manufacturing process of valsartan. ZHP is not saying that it was not possible to know that DMF could degrade.
 - e. ZHP never identified the nitrosamine impurities in connection with its 2011 Risk Assessment and therefore did not evaluate the nitrosamine impurities as part of any steps of the risk assessment process.

4. With regard to the Change Request Form identified as Exhibit 195 to the March 28/29, 2021 deposition of Peng Dong (copy of Exhibit attached hereto as Exhibit 1), ZHP states the following:
- a. The “Explanation Section” in Section 2 of the Change Request form on the page bearing Bates number ZHP01843067 provides a summary of the explanation for why the process change from the triethylamine hydrochloride process to the zinc chloride process was undertaken.
 - b. One of the reasons for the quality review described in Section 3 of the Change Request Form on the page bearing Bates number ZHP01843069 was to identify impurities due to the new process.
 - c. Section 3 of the Change Request Form on the page bearing Bates number ZHP01843070 provided that if this change was against cGMP code, it was supposed to be rejected.

Dated: May 13, 2022	<u>/s/ Richard T. Bernardo</u> Richard T. Bernardo SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP One Manhattan West New York, NY 10001-8602 richard.bernardo@skadden.com Jessica D. Miller SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP 1440 New York Avenue, N.W. Washington, D.C. 20005 jessica.miller@skadden.com Counsel for Defendant
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